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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,408	10/01/2003	Gilbert Rene Gonzales	PEDI-13	8069

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,408	GONZALES ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/28/2208*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-36 and 47-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-36 and 47-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RCE Acknowledged

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/28/2008 has been entered.

Status of Application

2. Acknowledgement is made of amendment filed on 05/28/2008. Upon entering the amendment, the claims 27 and 47 are amended. The pending claims are 27-36 and 47-50 are currently pending and presented for examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 27-36 and 47-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claims 27 and 47 to recite, a solid matrix having " at least one interior space with". This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. The specification discloses a pharmaceutical composition comprising a gas-dispersing component contains at least one first gas and is reactive with water or a vehicle containing water, to release the at least one first gas into the water or vehicle (see para 0024). However, the specification dose not recites, "at least one interior space with" as claimed.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 27-36 and 47-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "at least about" in claim 27 and 47 is a relative term which renders the claim indefinite. The term "at least about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term is unclear as to what the endpoints of the ranges/limitations are for the claim.

See Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), where the court held that claims reciting "at least about" were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." (See MPEP 2173.05 [R-5] "Relative Terminology").

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 27, 32-36 and 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Schobel (US 4,687,662).

With respect to claims 27, 32-36 and 47-50, the '662 patent discloses a method for oral administration of effervescent composition in the form of tablets or powders comprising a therapeutic agent, a granulating agent, a microparticulate effervescent component and an effervescent system which dissolve rapidly in water to yield an effervescent solution containing a completely dissolved therapeutic agent (see column 3, lines 10-12 and abstract). And also the microparticulate component of the effervescent system may be the carbonate containing material, the acid and mixtures thereof. And this microparticulate component when come in contact with water or saliva

will inherently release at least first gas. And also the granulating agent (solid matrix) may be selected from group consisting of water, alcohol, sucrose, hydroxypropyl cellulose and mixture thereof and causes slow disintegration of therapeutic agent and release gas (see column 4, lines 17-28). The effervescent system may comprise one or more components, preferably a carbonate containing material and an acid and mixtures thereof. The acids which may be employed are compounds capable of reacting with carbonate containing materials to cause the release of carbon dioxide when contacted with sufficient water (see column 5, lines 14-18 and lines 45+). The carbonate containing materials include inorganic carbonates, and particularly the alkali metal and ammonium carbonate materials (see col. 5 lines 48-60). The oral administration of effervescent composition advanced by Schobel provides granulating agent along with other additives such as lubricants, antiforming agents, flavoring agents, colorants, sweeteners and glidants may be used as is or formed into any desirable shape such as a tablet to render the composition to have interior space to hold first gas and a gas generating effervescent component suitable for providing the necessary amount of therapeutic agent. Since the essential elements of the cited reference are identical to the instant claims (i.e. gas dispersing component including a solid matrix, first gas contained therein, and a gas-generating effervescent component), would inherently have the same physiochemical properties as set forth in the instant application. As such the method for oral administration advanced by Schobel anticipates the instant claims set.

Applicant's arguments filed on 05/28/2008 have been fully considered but they are not persuasive.

Applicant-asserts that Schobel does not disclose a gas-dispersing component including a solid matrix having at least one interior space with at least one first gas contained therein

This is not found persuasive because in Schobel the therapeutic effervescent system comprising additional additives such as lubricants, sweeteners and glidants and thereof would constitute towards the formation of solid matrix and further the resultant blend is then formed into effervescent tablets. The additional sweetener includes sugars such as sucrose, glucose, invert sugar, fructose, and mixtures thereof. Saccharin and its various salts such as sodium or calcium salt; cyclamic acid and its various salts and sugar alcohols such as sorbitol, sorbitol syrup, mannitol, xylitol and the like (see col. 6, lines 25-45). Even though these additional additives are not listed as a solid matrix having a first gas, as recited in the instant claim, the same compounds (i.e. compounds that are employed to form solid matrix, the dispersing component which releases at least one first gas) would inherently have the same physiochemical properties as set forth in the instant application and accordingly serve as dispersing component to release at least one first gas. And further, effervescent composition advanced by Schobel provides granulating agent along with other additives such as lubricants, antiforming agents, flavoring agents, colorants, sweeteners and glidants may be used as is or formed into any desirable shape such as a tablet to render the composition to

have interior space to hold first gas and a gas generating effervescent component suitable for providing the necessary amount of therapeutic agent.

Gleaning from applicant's specification at page 5, lines 1-11 a first gas is generated by contact of gas-dispersing component to release or erupt gas. Thus, this component generally comprises water-soluble ingredients, such as carbohydrates, saccharides of simple sugars and sugar derivates, non-sugar sweetener, non-sweeteners, and the like. Similarly the prior art, Schobel discloses carbohydrates such as sugars, sucrose, glucose, invert sugar, fructose, and mixtures thereof; saccharin and its various salts and sugar alcohols such as sorbitol, sorbitol syrup, mannitol, xylitol, and the like (col. 6, lines 25-40). These components in contact with water would also generate a gas, so that Schobel discloses the first gas.

And further, the effervescent system comprises a carbonate containing material and an acid. When introduced to water, the carbonate containing compound reacts with the acidifying agent to produce a rapid evolution of carbon dioxide gas. This rapid evolution of gas stirs/agitates the solution dispersing the therapeutic agent. The stirring/agitating is intended to solubilize the therapeutic agent. This meets the limitation of an effervescent component that generates a second gas. The essence of dispersing a first gas and the gas generating component that reacts to produce second gas, and both gases of which are released into the liquid vehicle, will enhance distribution and dispersion of the medicament to form a clear solution. Therefore, Schobel does, not only disclose a first gas but also discloses the gas-generating effervescent component to generate a second gas.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 27-36 and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al (US 6,071,539) in view of Leon Kremzner et al (US 3,012893).

Robinson discloses a solid pharmaceutical dosage form adapted for direct oral administration. And pharmaceutical composition comprises an effervescent granule having a controllable rate of effervescence prepared by hot-melt extruding (i) an acidic agent, (ii) an alkaline agent, and (iii) a hot-melt extrudable binder which is capable of forming a eutectic mixture with the acidic agent (see abstract and col. 2 line 50-55). And acidic agent can serve as a proton source and can react with the alkaline agent to from a gas causing a solution containing them to effervesce and, include tartaric acid, citric acid, maleic acid, fumaric acid, alpha hydroxyl acids, ascorbic acid, amino acids and

their alkali hydrogen salts (see col. 3 lines 52-65+). And alkaline agent can be a carbon dioxide gas precursor, an oxygen gas precursor or a chlorine dioxide gas precursor (see col. 4 line 20-38). And hot-melt extrudable binders is one that is sufficiently rigid at standard ambient temperature and pressure but is capable of deformation or forming a semi-liquid state under elevated heat or pressure, include acacia, tragacanth, gelatin, cellulose materials such as methyl cellulose and sodium carboxy methyl cellulose, alginic acids and salts, guar gum, polysaccharide, bentonites, sugars, invert sugars, poloxamers and combinations of the above and the like (see col. 5 lines 32-44). And effervescent granules includes formulations containing active ingredients such as a therapeutic compound, a flavoring agent, a sweetening agent, a vitamin, and other such compounds and effervescent granules can be formulated into a variety of forms such as a tablet, capsule, suspensions, reconstitutable powder and suppository (see col. 7 line 36-49).

Robinson meets the claim limitation as discussed above but fails to include a gas-dispersing component included in a solid matrix therein.

Leon Kremzner discloses a method of enclosing a gas within a solid matrix to yield a gas-containing solid which is substantially stable at room temperature for extended periods of time comprising a solidified fusible sugar containing therewithin a gas (see col. 1 line 29-35 and claim 1). And fusible sugars include sugars and their derivatives such as sugar alcohols and sugar acids, monosaccharide sugars, disaccharide sugars, polysaccharide sugars and the like (sol. 2 line 11-20). And incorporation of gas (carbon dioxide, nitrogen, or air) into the fusible sugar under fusion

producing conditions may be effected by various techniques (see col. 3 lines 8-21). And product (gas-containing solid matrix) may be employed as a carbonating agent in beverages, as a leavening agent in baking, and can be used as a carbonated hard candy and product when placed in mouth, it disintegrates with a mild popping sound and liberates gas on contact with liquid and under pressure as it dissolves (see col. 3 line 54-65+).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combination of a medicament, a gas-dispersing component including a solid matrix and a gas-generating effervescent component effective to aid in the rapid and complete disintegration of the tablet in effervescent composition, as taught by Robinson, combine it with the gas-dispersing component contained within the solid matrix, as taught by Leon Kremzner, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Robinson teaches an effervescent composition comprising, a mixture incorporating a water and/or saliva activated effervescent granule having a controllable rate of effervescence and a therapeutic compound and further, combination of effervescent granules with the other ingredients can provide effective taste masking of particularly poor tasting compounds.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/ Jagadishwar R Samala

Supervisory Patent Examiner, Art Unit 1618

Examiner
Art Unit 1618

sjr